

EXHIBIT 1

3RD DISTRICT CT- SILVER SUMMIT
SUMMIT COUNTY, STATE OF UTAH

GALE PACE vs. WRIGHT MEDICAL TECHNOLOGY INC et al.

CASE NUMBER 210500393 Product Liability

CURRENT ASSIGNED JUDGE
RICHARD MRAZIK

PARTIES

Plaintiff - GALE PACE

Defendant - WRIGHT MEDICAL GROUP INC

Defendant - WRIGHT MEDICAL TECHNOLOGY INC

ACCOUNT SUMMARY

Total Revenue Amount Due:	625.00
Amount Paid:	0.00
Amount Credit:	0.00
Balance:	625.00

REVENUE DETAIL - TYPE: COMPLAINT - NO AMT S

Original Amount Due:	375.00
Amended Amount Due:	375.00
Amount Paid:	0.00
Amount Credit:	0.00
Balance:	375.00

REVENUE DETAIL - TYPE: JURY DEMAND - CIVIL

Original Amount Due:	250.00
Amended Amount Due:	250.00
Amount Paid:	0.00
Amount Credit:	0.00
Balance:	250.00

CASE NOTE

PROCEEDINGS

11-09-2021 Case filed by bridgetb
11-09-2021 Judge RICHARD MRAZIK assigned.
11-09-2021 Note: Tier initially set to 3
11-09-2021 Fee Account created Total Due: 375.00
11-09-2021 Fee Account created
11-09-2021 Fee Account created Total Due: 250.00
11-09-2021 Fee Account created
11-09-2021 Filed: Complaint
11-09-2021 Filed: Cover Sheet

Gale Pace
1452 South Hoytsville Road
Coalville, UT 84017
Telephone: (435) 336-2560
Email: kateandgale@gmail.com

Filing as Pro Se Plaintiff

**IN THE THIRD JUDICIAL DISTRICT OF COURT
SALT LAKE COUNTY, STATE OF UTAH**

GALE PACE,

Plaintiff,

v.

WRIGHT MEDICAL TECHNOLOGY, INC., a
Delaware Corporation;

and

WRIGHT MEDICAL GROUP, INC., a
Delaware Corporation;

Defendants.

COMPLAINT

Civil No.: _____

Tier 3

Jury Trial Requested

Plaintiff, GALE PACE, alleges and complain against WRIGHT MEDICAL TECHNOLOGY, INC., and WRIGHT MEDICAL GROUP, INC., (collectively referred to herein as “Defendants” or “Wright Medical”), as follows:

INTRODUCTION

1. This is an action brought by Plaintiff for injuries arising out of the defective metal-on-metal Wright Medical Total Hip System (“Wright Hip System”), which includes CONSERVE®

and PROFEMUR® Hip System components, Plaintiff received as part of total hip replacement surgery.

2. On February 7, 2005, Plaintiff received a Wright Hip System as part of a left total hip replacement surgery. On and before the date of Plaintiff's implantation surgery, Defendants knew or should have known based on reports received from orthopedic surgeons around the United States that the Wright Hip System was defective and likely to fail. Defendants concealed their adverse information and continued to represent to Plaintiff, his healthcare providers, and the public that the Wright Hip System, including the CONSERVE® Hip System, was a safe, effective medical device with a low failure rate.

3. After implantation of the Wright Hip System, Plaintiff began to experience the painful effects of the product's defective design and manufacture. Plaintiff began suffering persistent pain and decreased mobility, both worsening over time. While Plaintiff's physicians searched for the cause of Plaintiff's pain, Plaintiff continued to endure persistent, debilitating pain and decreased mobility. Plaintiff began suffering emotional distress as a result of the defective product.

4. On January 17, 2019, Plaintiff was required to undergo revision surgery to remove and replace the defective Wright Hip System in his left hip.

5. Revision hip replacement surgery to remove and replace the failed Wright Hip System with a new implant is a complex, risky, and painful procedure. Revision surgeries are generally more complex than original hip replacement surgeries as there is less bone available to attach the new implant. Revision surgeries also are usually longer than the original hip replacement procedure and have a higher rate of complications.

6. After his revision hip replacement surgery, Plaintiff endured a long recovery that was both physically and emotionally painful. Further, Plaintiff has had to live, and continued to live, with a greater risk of future complications as a revised hip implant presents a much higher risk of dislocation than an original implant.

PARTIES

7. Plaintiff, GALE PACE, is a competent adult, a resident, and a citizen of Coalville, Utah.

8. Defendant WRIGHT MEDICAL TECHNOLOGY, INC., is, and at all times herein mentioned was, a Delaware corporation with its principal place of business in the State of Tennessee.

9. At all relevant times, Defendant WRIGHT MEDICAL TECHNOLOGY, INC. regularly conducted business throughout the United States, in the State of Utah, and in Salt Lake County, Utah.

10. Defendant WRIGHT MEDICAL GROUP, INC., is, and at all times herein mentioned was, a Delaware corporation with its principal place of business in the State of Tennessee.

11. At all relevant times, Defendant WRIGHT MEDICAL GROUP, INC. regularly conducted business throughout the United States, in the State of Utah, and in Salt Lake County, Utah.

12. Defendant WRIGHT MEDICAL TECHNOLOGY, INC. is a wholly-owned subsidiary of WRIGHT MEDICAL GROUP, INC.

13. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of its Co-Defendants.

14. Defendant WRIGHT MEDICAL TECHNOLOGY, INC. and defendant WRIGHT MEDICAL GROUP, INC. shall hereafter, jointly and severally, be referred to as “Defendant(s).”

15. Defendants regularly solicit business or engage in other persistent courses of conduct in the State of Utah, and derive substantial revenue from the sale of products or services that are used or consumed in the State of Utah.

JURISDICTION AND VENUE

16. The events giving rise to this dispute occurred in Salt Lake City, Utah.

17. This Court has jurisdiction over this case pursuant to Utah Code § 78A-5-102(1).

18. Venue is proper within this Court pursuant to Utah Code § 78B-3-307(1) and (3).

19. This case falls under Tier 3 for standard discovery purposes as the amount of damages is more than \$300,000.00.

BACKGROUND

20. The hip joint, connecting the femur and pelvis, consists of a femoral head rotating within the acetabulum. The femoral head is a ball-like structure at the top of the femur. The acetabulum is a cup-shaped bone structure at the bottom of the pelvis. Over time, the cartilage that cushions the rotation of the femoral head and acetabulum against each other breaks down. When the cartilage between the femoral head and acetabulum is depleted, the femoral head rubs directly against the acetabulum, causing extreme pain and immobility, necessitating a total hip replacement surgery.

21. In a total hip replacement, an artificial hip joint is installed to replace the body's natural joint. Usually, the artificial joint is made of metal and plastic and consists of four parts: (1) an acetabular shell; (2) a plastic liner; (3) a femoral head; and (4) a femoral stem. In most hip replacement systems, the femoral head forms the hip joint when it is placed inside the plastic liner and acetabular shell.

22. Defendants and others designed and developed the Wright Hip System. The Wright Hip System differs from most hip implants in that the metal femoral head is in direct contact with a metal acetabular cup, resulting in a metal-on-metal construct.

23. Defendants knew that previously attempted metal-on-metal hip replacement prostheses had failed in the 1960s and 1970s. They also knew, by no later than 1995, that metal debris, corrosion, and release of ions resulting from the movement of a metal-on-metal artificial hip joint can cause adverse local tissue reactions, inflammation, pseudotumors, osteolysis, and bone and tissue necrosis, among other problems, leading to the failure of the prosthesis and revision surgery.

24. Nonetheless, in an attempt to capture market share and profits over its competitors,

Wright aggressively marketed the Wright Hip System, particularly the CONSERVE[®] Hip System.

25. Despite its unorthodox design, Defendants did not properly test the Wright Hip System for safety, efficacy, and durability. Other metal-on-metal prosthetic hip device manufacturers carefully screen, select, and train orthopedic surgeons on proper implant procedures for their respective devices. Instead, Defendants aggressively marketed, promoted, and encouraged orthopedic surgeons in the United States to use the Wright Hip System without screening, selecting, or training the surgeons on how to implant the Wright Hip System.

26. Wright designed a marketing campaign aimed at orthopaedic surgeons with the goal of de-criminalizing and downplaying the dangers of metal ions – a campaign that provided information directly contrary to Wright’s own knowledge. And, despite Wright’s knowledge that an increase in activity level for patients with metal-on-metal hip implants also increased the production of metal debris, it marketed the Wright Hip System, including the CONSERVE[®] Hip System, as safe and appropriate for use in younger, more active patients like Plaintiff.

27. While Wright wanted to market its Wright Hip System in the United States, it did not want to endure the long and expensive FDA approval process. Instead, Wright exploited a loophole in FDA regulations that would allow its device to enter the U.S. market without proper testing or approval. Wright represented that the CONSERVE[®] Hip System design was substantially equivalent to other hip replacement products already on the market.

28. While representing to the FDA that its CONSERVE[®] Hip System was “substantially equivalent” to other hip replacement products, Wright omitted the CONSERVE[®] Hip System’s critical distinguishing features. The CONSERVE[®] Hip System’s femoral head has a larger circumference than the industry standard. Also, the acetabular cup departs from industry standards in that it (1) is thinner; (2) has a smaller circumference; (3) is double-heat treated rather than single-heat treated; (4) has an exterior shell that lacks reliable bone ingrowth materials; (5) offers no obvious means of fixation other than the expectation that the patient’s bone will grow into the porous exterior of the cup; and (6) has a low clearance which spreads the contact area out closer to the edge of the cup resulting in increased friction from the lack of lubrication entering

the cup.

29. Wright utilized misrepresentations that contradicted its own knowledge regarding activity levels and metal ions to drive sales of the CONSERVE[®] Hip System. Despite knowing that increased activity would lead to increased wear, Wright directed its marketing (via websites, journal ads, brochures, pamphlets, testimonials, endorsements, newspaper articles, and other means) to surgeons and younger, more active consumers who wanted to return to physical activities, including but not limited to:

- a) Surfing;
- b) Skiing;
- c) Martial Arts, including competitive levels;
- d) Hockey;
- e) Ice skating;
- f) Motorcycling;
- g) Horseback rides;
- h) Tennis;
- i) Golf;
- j) Soccer;
- k) Football;
- l) Mountain climbing;
- m) Running, including marathons and triathlons;
- n) Hiking;
- o) Biking, including trail riding; and
- p) Swimming.

30. While representing to the FDA that its CONSERVE[®] Hip System was “substantially equivalent” to other hip replacement products, Wright omitted the CONSERVE[®] Hip System’s critical distinguishing features. The CONSERVE[®] Hip System’s femoral head has a larger circumference than the industry standard. Also, the acetabular cup departs from industry

standards in that it (1) is thinner; (2) has a smaller circumference; (3) is double-heat treated rather than single-heat treated; (4) has an exterior shell that lacks reliable bone ingrowth materials; (5) offers no obvious means of fixation other than the expectation that the patient's bone will grow into the porous exterior of the cup; and (6) has a low clearance which spreads the contact area out closer to the edge. Shortly after the U.S. launch of the Wright Hip System, Defendants began receiving complaints from doctors reporting Wright Hip System, including CONSERVE® Hip System, failures. By 2005, Defendants had received such reports regarding their CONSERVE® (and Profemur®) lines. Defendants failed to disclose or actively concealed these adverse reports from doctors and patients, including Plaintiff and Plaintiff's orthopedic surgeon, and continued to promote the Wright Hip System, including the CONSERVE® Hip System, as a safe and effective device.

31. Before Plaintiff's 2005 hip replacement surgery, Defendants knew or should have known that the Wright Hip System, including the CONSERVE® Hip System, was failing frequently and causing serious post-implant complications for many patients. Those complications arising out of implantation with the Wright Hip System that Defendants knew or should have known about included, but were not limited to: bone cysts; pseudo-tumors; metallosis and osteolysis; high levels of metal ions, such as chromium and cobalt, in the bloodstream; detachment, disconnection, and/or loosening of the acetabular cup; loosening of the femoral component; and other complications requiring revision surgery. Despite being armed with such knowledge, Defendants concealed the true risks associated with the Wright Hip System, including the CONSERVE® hip implants. Instead, they continued to market, defend, and promote the Wright Hip System, including the CONSERVE® Hip System.

32. When Wright received complaints about metallosis, adverse local tissue reactions, inflammation, pseudotumors, osteolysis, and bone and tissue necrosis, coupled with early failure of the Wright Hip System, including the CONSERVE® components, Wright ignored the complaints, blamed the implanting surgeons, and continued to promote and sell the Wright Hip System.

33. From as early as 1996 through the present, Dr. Amstutz served as a consultant for Wright. Dr. Amstutz is one of the innovators and developers of the CONSERVE[®] hip surface arthroplasty utilizing metal-on-metal bearing technology.

34. Dr. Amstutz and Wright representatives continued to market the superiority of the Wright Hip System, including the CONSERVE[®] Hip System, despite their awareness of numerous, serious complications and alarmingly high failure rates. Dr. Amstutz and Wright representatives concealed their knowledge of the Wright Hip System's unacceptably high failure rate.

35. Despite legal and moral obligations to cease promoting, marketing, selling, and defending the Wright Hip System, including CONSERVE[®] Hip System, upon awareness of its serious risks, Dr. Amstutz and Wright representatives did not notify physicians, including Plaintiff's orthopedic surgeon, of the device's propensity to fail and cause other serious complications.

36. Defendants had a strong monetary motive not to reveal the dangers associated with the Wright Hip System. In 2010, alone, Wright's sales revenue was over \$518 million, with about \$176 million comprising of sales from their hip products, making it one of its parent company's most profitable groups. Likewise, Dr. Amstutz collected millions of dollars in royalties and consulting fees from Wright for designing, marketing, promoting, and defending the Wright Hip System, including the CONSERVE[®] Hip System. For example, in his consulting agreement with Wright, Dr. Amstutz was promised a consulting salary and a royalty of 5% of all net sales from Wright's CONSERVE[®] hip implants.

37. As a result of Wright's aggressive and misleading marketing, failure to follow FDA requirements, and failure to acknowledge and warn surgeons, patients, and the public about known problems with metal-on-metal hip replacements in general and the Wright Hip System, including CONSERVE[®] Hip System, in particular, Plaintiff and many others, received defective and unreasonably dangerous CONSERVE[®] hip implants.

38. Subsequently, as a direct and proximate result of the design, manufacture, and

composition of the device, Plaintiff's Wright Hip System detached, disconnected, created metallic debris, released metal ions, and/or loosened from Plaintiff's acetabulum. As a result, the Wright Hip System forced Plaintiff to live with debilitating pain, decreased mobility, and emotional distress.

39. Plaintiff, like many other patients who received these defective medical devices, has endured unnecessary pain and suffering, debilitating lack of mobility, loosening through osteolysis, inflammation causing damage or death to tissue and bone around the implant, metallosis, toxicity, and a subsequent more difficult revision surgery to replace the defective Wright Hip System, giving rise to additional pain and suffering, prolonged recovery time, and an increased risk of complications and death from surgery.

40. Defendants recklessly, knowingly, intentionally, and fraudulently misrepresented to the medical community and the general public, including Plaintiff and Plaintiff's healthcare providers, that the Wright Hip System, including the CONSERVE® and PROFEMUR® components used in Plaintiff's 2005 hip replacement procedure, was safe and effective for its intended use.

41. Defendants recklessly, knowingly, intentionally, and fraudulently concealed and suppressed adverse information relating to the safety and performance of the Wright Hip System from the medical community and the general public, including Plaintiff and Plaintiff's healthcare providers.

42. Defendants' misrepresentations were communicated to the medical community and the general public, including Plaintiff and Plaintiff's healthcare providers, with the intent that the medical community and general public, including Plaintiff and Plaintiff's healthcare providers, would rely on their representations in selecting the Wright Hip System.

43. Specifically, Defendants misrepresented and actively concealed material facts regarding the safety and performance of the Wright Hip System, including, but not limited to:

- a) the Wright Hip System was not as safe as other available hip implant devices;

- b) the Wright Hip System had an unacceptably high rate of failures requiring revision surgery;
- c) the safety and performance of the Wright Hip System was not adequately tested and/or known by Defendants;
- d) patients implanted with the Wright Hip System were at increased risk of experiencing painful and debilitating product failure and were more likely to undergo revision surgery than patients using other hip implant devices;
- e) the Wright Hip System was designed, manufactured, marketed, promoted, distributed, and sold negligently, defectively, and/or improperly;
- f) the design of the Wright Hip System increased the wear between the femoral component and the acetabular component, as compared to other hip implant products;
- g) metal corrosion was more likely to occur, and would occur with greater severity, as compared to other hip replacement products;
- h) surgical implantation according to recommended specifications was substantially more difficult than other hip replacement products, and proper surgical implantation was substantially less likely to occur;
- i) metal ion debris would be released into the patient's body; and
- j) safer alternatives were available.

44. Defendants' misrepresentations were communicated to the medical community and the general public, including Plaintiff and Plaintiff's healthcare providers, with the intent that the medical community and general public, including Plaintiff and Plaintiff's healthcare providers, would rely on their representations in selecting the Wright Hip System.

45. To Plaintiff's detriment, Plaintiff and Plaintiff's healthcare provider justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment to recommend, purchase, implant, and/or use the Wright Hip System.

46. As a direct, legal, proximate, and producing result of Defendants' misrepresentation

and active concealment of material facts, Plaintiff has suffered injuries as set forth herein.

47. Plaintiffs file their lawsuit within two years of first suspecting that the Wright Hip System was the cause of any appreciable harm sustained by Plaintiff. Plaintiff first suspected that the cause of his injuries was the defective Wright Hip System on or about January 2020, when Plaintiff had to undergo his first hip revision surgery for his left hip. By the exercise of reasonable diligence, Plaintiff could not have discovered the wrongful cause of Plaintiff's injuries at an earlier time because when Plaintiff's injuries were discovered, their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, the cause of Plaintiff's injury or the tortuous nature of the conduct causing injury until less than two years prior to the initial filing of their action. Additionally, Plaintiff was prevented from discovering their information sooner because Defendants misrepresented, and continues to misrepresent, to the public and the medical community that the Wright Hip System, including the CONSERVE® Hip System, did not have a propensity to fail or cause other serious complications. Further, Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

FIRST CLAIM FOR RELIEF

(Strict Product Liability (Defective Design))

48. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

49. Defendants were engaged in the business of designing, manufacturing, marketing, selling, and distributing orthopaedic hip implants and did design, manufacture, distribute, market, and sell the product implanted in Plaintiff.

50. Defendants each had a duty to place into the stream of commerce, manufacture, distribute, market, promote, and sell the Wright Hip Implant System so that it and its component parts were neither defective nor unreasonably dangerous when put to the use for which they were designed, manufactured, distributed, marketed, and sold and for all foreseeable uses.

51. Defendants sold, distributed, supplied, and/or promoted the Wright Hip System to Plaintiff and Plaintiff's physician.

52. Defendants expected the Wright Hip Implant System that it was selling, distributing, supplying, manufacturing, and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the State of Utah, including Plaintiff and his implanting physician, with no change in its condition from the time of its manufacture through its implantation.

53. The metal-on-metal Wright Hip System orthopaedic implant did not perform as safely as an ordinary consumer would have expected at the time of use.

54. At the time the Wright Hip System left the possession of Defendants and the time the Wright Hip System entered the stream of commerce, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

- a. The Wright Hip System was not reasonably safe as intended to be used;
- b. the Wright Hip System had an inadequate design for the purpose of hip replacement;
- c. the Wright Hip System contained unreasonably dangerous design defects, including an inherently defective design;
- d. the Wright Hip System's unstable and defective modular design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;
- e. the Wright Hip System was not appropriately or adequately tested before its distribution; and;
- f. the Wright Hip System has an unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use of the Device.

55. Plaintiff used the Wright Hip System for its intended purpose as a hip replacement device and in a reasonably foreseeable manner.

56. As a direct and proximate result of one or more of the foregoing design issues, the Wright Hip System proximately caused Plaintiff to suffer and sustain injuries. Additionally, these design issues have directly and proximately caused and continue to cause Plaintiff to endure pain and suffering in body and mind. The design defects alleged

herein have and will also continue to cause Plaintiff to incur expense and loss of opportunities in his efforts to treat his injuries. Plaintiff has lost and will continue to lose income because of his injuries. He has been and will be unable to attend to his normal affairs and duties.

57. In addition, Defendants' defective and inadequate warnings are, at the very least, the result of conduct that manifests a knowing and reckless indifference toward, and a disregard of the rights of others. Accordingly, pursuant to Utah Code § 78B-8-201, Plaintiff is entitled to an award of punitive damages.

SECOND CLAIM FOR RELIEF

(Strict Product Liability (Warnings Defect/Failure to Warn))

1. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

2. Defendants were required to warn about any danger from the Wright Hip System's foreseeable use of which they knew or should have known. Defendants knew or should have known and warned Plaintiff and/or Plaintiff's implanting surgeon about the following dangers, among others:

- a. The Wright Hip System design puts the metal femoral ball directly in contact with the metal acetabular cup, resulting in the production of metal-on-metal wear debris;
- b. The amount of metal-on-metal wear debris generated increases with a patient's activity level;
- c. Patients can have adverse reactions to metal debris, including but not limited to osteolysis and inflammation, resulting from foreseeable use of the Wright Hip System;
- d. The Cobalt-Chromium wear debris, corrosion and metal ions resulting from foreseeable use of the Wright Hip System are toxic and can cause adverse local tissue reactions, inflammation, and failure of the Wright Hip System
- e. The Wright Hip System warnings did not disclose that the device was inadequately

tested or that Wright failed to test the effects of Cobalt-Chromium metal debris on human tissues;

- f. The Wright Hip System warnings failed to convey adequate postmarketing warnings regarding the risk, severity, scope, and/or duration of the dangers posed by the device; and
- g. The Wright Hip System warnings failed to alert consumers to the dangers it posed and failed to give them the information necessary to avoid or mitigate those dangers.

3. The metal-on-metal Wright Hip System had potential risks that were known at the time of manufacture, distribution, or sale.

4. The warnings given to Plaintiff and Plaintiff's implanting physician about the dangers the Wright Hip System posed to consumers were inadequate and were diluted and contradicted by its marketing materials.

5. In addition, the Instructions for Use for the Wright Hip System was a generic set of instructions for all of its hip prostheses and did not warn about specific metal-on-metal issues.

6. Defendants, as designer, manufacturer, marketer and distributor of medical devices are held to the level of knowledge of an expert in its field.

7. Plaintiff and Plaintiff's implanting physician did not have substantially the same knowledge as the Wright Hip System's designer, manufacturer or distributor: Wright Medical.

8. For the reasons noted above, Defendants failed to provide an adequate warning at the time the Wright Hip System was manufactured, distributed, and sold (and implanted).

9. Defendants' failure to provide an adequate warning made the Wright Hip Systems defective and unreasonably dangerous.

10. The lack of adequate warning proximately caused Plaintiff to suffer and sustain injuries. Additionally, the inadequate warnings have caused and continue to cause Plaintiff to endure pain and suffering in body and mind. The design defects alleged herein have and will also continue to cause Plaintiff to incur expense and loss of opportunities in his efforts to treat his

injuries. Plaintiff has lost and will continue to lose income because of his injuries. He has been and will be unable to attend to his normal affairs and duties.

11. In addition, Defendants' defective and inadequate warnings are, at the very least, the result of conduct that manifests a knowing and reckless indifference toward, and a disregard of the rights of others. Accordingly, pursuant to Utah Code § 78B-8-201, Plaintiff is entitled to an award of punitive damages.

THIRD CLAIM FOR RELIEF

(Strict Product Liability (Manufacturing Defect))

1. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

2. The Wright Hip Systems, manufactured and supplied by Defendants, were defective in that, when they left the hands of Defendants, the device deviated, in its construction or quality, from the manufacturer's specifications or planned design in a manner that rendered it defective and unreasonably dangerous.

3. Defendants were engaged in the business of designing, manufacturing, marketing, selling, and distributing orthopaedic hip implants and did design, manufacture, distribute, market, and sell the product implanted in Plaintiff.

4. Defendants each had a duty to place into the stream of commerce, manufacture, distribute, market, promote, and sell the Wright Hip Implant System so that it and its component parts were neither defective nor unreasonably dangerous when put to the use for which they were designed, manufactured, distributed, marketed, and sold and for all foreseeable uses.

5. The metal-on-metal Wright Hip System orthopaedic implant contained manufacturing defects when it left the possession of Defendants without a substantial change in the condition in which it was sold, and each of them.

6. The manufacturing defects rendered the Wright hip implant unreasonably dangerous as to its characteristics by making the product dangerous to an extent beyond that which

would be contemplated by the ordinary user of the product considering the product's characteristics, risks, dangers, and uses, together with any actual knowledge, training, or experience that the user had.

7. Plaintiff used the metal-on-metal Wright Hip System orthopaedic implant in a reasonably foreseeable manner.

8. The defects in the metal-on-metal Wright Hip System orthopaedic implant, were a substantial factor in causing Plaintiff's harm.

9. As a direct and proximate result of being implanted with the metal-on-metal Wright Hip System orthopaedic implant, and the negligent acts and omissions of Defendants, and each of them, Plaintiff suffered the harm described herein and incorporated herein by reference.

FOURTH CLAIM FOR RELIEF

(Negligence/Gross Negligence)

10. Plaintiff incorporates by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

11. Defendants, and each of them, owed Plaintiff a duty to exercise reasonable care in the testing, manufacturing, designing, formulating, constructing, rebuilding, fabricating, producing, marketing, assembling, selling and/or distributing of the metal-on-metal Wright Hip System orthopaedic implant such that it would be reasonably safe for its intended use.

12. Defendants, and each of them, knew or had reason to know that Plaintiff, as a member of the general public for whose use the metal-on-metal Wright Hip System implant was placed into interstate commerce, would be likely to use the metal-on-metal Wright Hip System implant in the manner described in this Complaint.

13. Defendants, and each of them, knew or reasonably should have known of the danger associated with the manner and circumstances of Plaintiff's foreseeable use of the metal-on-metal Wright Hip System implant, which dangers would not be obvious to a reasonable consumer who Wright expected to use the Conserve Hip Implant System

14. Defendants, and each of them, breached their duties by failing to exercise reasonable care in the testing, manufacturing, designing, formulating, constructing, rebuilding, fabricating, producing, marketing, assembling, selling, distributing or issuance of warnings for the metal-on-metal Wright Hip System orthopaedic implant, and providing products that Defendants knew, or should have known, of the likelihood and severity of potential harm from the products, including, but not limited to, pain, popping, grinding, lack of mobility, metal sensitivity, loosening of the prosthesis, infection, dislocation, bone fracture, high metal ion levels in their bloodstreams, cyst formation, and the necessity for revision surgery to explant the hip device and replace it with other products. Moreover, the likelihood and severity of harm was not outweighed by the lesser burden of taking safety measures to reduce or avoid that harm.

15. Wright knew or reasonably should have known of the danger associated with the manner and circumstances of Plaintiff's foreseeable use of the Wright Hip System which dangers would not be obvious to a reasonable consumer who Defendants expected to use the Wright Hip System.

16. Defendants failed to exercise reasonable care in its design and testing of, and warnings for, the Wright Hip System. Wright's negligence and gross negligence have caused and continue to cause Plaintiff to endure pain and suffering. The design defects alleged herein have and will also continue to cause Plaintiff to incur expense and loss of opportunities to treat his injuries. Plaintiff has lost and will continue to lose income because of his injuries. He has been and will be unable to attend his normal affairs and duties.

FIFTH CLAIM FOR RELIEF

(Negligence Per Se)

17. Plaintiff incorporates by reference, as is fully set forth herein, each and every allegation set forth in the preceding paragraphs.

18. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising,

preparing for use, and warning of the risks and dangers of the metal-on-metal Wright Hip System implant devices.

19. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence per se.

20. Plaintiff, as a purchaser of the metal-on-metal Wright Hip System implant, is within the class of persons the statutes and regulations (described above) are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

21. As a direct and proximate result of Defendants' wrongful conduct, constituting negligence per se, Plaintiff has suffered serious physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, for which he is entitled to declaratory relief, and compensatory and equitable damages in an amount to be determined by the trier of fact.

SIXTH CLAIM FOR RELIEF

(Breach of Implied Warranties)

1. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

2. At the time Plaintiff purchased and was implanted with the device described herein, Defendants, and each of them, were in the business of manufacturing, designing, formulating, constructing, rebuilding, fabricating, producing, marketing, assembling, selling and/or distributing orthopaedic hip implants or by their occupations held themselves out as having special knowledge or skill regarding orthopaedic hip implants.

3. Defendants, as designers, manufacturers, marketers and distributors of hip-implant devices, held itself out as having special knowledge or skill regarding hip implants and experts in their field.

4. The Wright Hip System, at the time of sale to Plaintiff, was not reasonably fit for the ordinary purposes for which hip implants are used.

5. Defendants had reason to know to that Plaintiff was buying the Wright Hip System for the particular purpose of hip replacement surgery and that Plaintiff was relying on Wright's skill or judgment to select or furnish a suitable hip implant.

6. The Wright Hip System was defective, and its condition rendered it defective and unreasonably dangerous, as described above, and unfit for the particular purpose for when Plaintiff purchased it.

7. As a result of the defective nature of the Wright Hip System and its failure to comply with the implied warranties of merchantability and fitness for a particular purpose, Plaintiff has been and will continue to be harmed, including pain and suffering in body and mind, past and future medical expenses, lost income, and his inability to attend to his normal affairs and duties.

SEVENTH CLAIM FOR RELIEF

(Breach of Express Warranties)

8. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

9. Defendants, and each of them, made a statement of fact or a promise to, which was received by Plaintiff, that metal-on-metal Wright Hip System orthopaedic implant was a state of the art orthopaedic hip implant that would last approximately 15-20 years; would not cause pain, popping, grinding, lack of mobility, metal sensitivity, loosening of the prosthesis, infection, dislocation, bone fracture, high metal ion levels in their bloodstreams, cyst formation, or the necessity for revision surgery within a couple of years to explant the metal-on-metal Wright Hip System orthopaedic implant and replace it with another orthopaedic implant.

10. The express warranties, guarantees, representations, statements, and claims made by Defendants were a part of the basis for Plaintiff's use of the Device and he relied on these warranties in deciding to use the Device.

11. The express warranties, guarantees, representations, statements, and claims made by Defendants were a part of the basis for Plaintiff's implanting surgeon's use of the Device and he relied on these warranties in deciding to use the Device.

12. At the time of the making of the express warranties, guarantees, representations, statements, and claims, Defendants had knowledge of the purpose for which these products would be used, and warranted the same to be in all respects safe, effective and proper for such purpose.

13. The metal-on-metal Wright Hip System orthopaedic implant did not perform as stated or promised by Defendants, and each of them, insofar as they were defective and did not conform to the express statements made by Defendants, and each of them.

14. Plaintiff and his implanting surgeon as the learned intermediary, each reasonably relied up Defendants' express warranties, guarantees, representations, statements, and claims.

15. Plaintiff used the Wright Hip System for its intended purpose and in a reasonably foreseeable manner.

16. As a direct and proximate result of Defendants breach of express warranties, Plaintiff suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future.

17. As a direct and proximate result of Defendants breach of express warranties, Plaintiff suffered and will continue to suffer injuries, damages and losses and is entitled to damages in an amount determined by the trier of fact.

EIGHTH CLAIM FOR RELIEF

(Fraudulent Concealment)

18. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

19. Defendants, and each of them, as designers, manufacturers, marketers and distributors of hip-implant devices, held itself out as having special knowledge or skill regarding hip implants and expert in its field.

20. Defendants, and each of them, had a duty to disclose to Plaintiff all material facts about the metal-on-metal Wright Hip System orthopaedic implant.

21. Upon information and belief, Defendants, and each of them, concealed or suppressed material facts about the metal-on-metal Wright Hip System orthopaedic implant. Specifically, Defendants concealed the material fact that the metal-on-metal Wright Hip System orthopaedic implant would fail before the standard 15-20 year hip orthopaedic implant lifespan and cause pain, popping, grinding, lack of mobility, metal sensitivity, loosening of the prosthesis, infection, dislocation, bone fracture, high metal ion levels in their bloodstreams, cyst formation, and the necessity for revision surgery to explant the metal-on-metal Wright Hip System orthopaedic implant and replace it with other products.

22. Upon information and belief, Defendants, and each of them intentionally concealed or suppressed the material facts with the intent to defraud Plaintiff.

23. Plaintiff was unaware of these material facts and would not have acted as Plaintiff did in allowing the metal-on-metal Wright Hip System orthopaedic implant to be implanted if Plaintiff had known of the concealed or suppressed material facts.

24. Neither Plaintiff nor Plaintiff's implanting physician knew that the Wright Hip System was defective or unreasonably dangerous, that it may have been illegally marketed or sold, that elevated Chromium and Cobalt ions had deleterious effects, or that the Conserve Hip Implant System was not appropriate for use in active patients like Plaintiff.

25. Defendants' fraudulent concealment and non-disclosure were a substantial factor in causing Plaintiff's injuries, including pain and suffering, past and future medical expenses, loss of income, and his inability to attend his normal affairs and duties.

26. In addition, Defendants' fraudulent concealment and non-disclosure are, at the very least, conduct that manifests a knowing and reckless indifference toward and a disregard of the rights of others. Accordingly, Plaintiff is entitled to an award of punitive damages.

EIGHTH CLAIM FOR RELIEF

(Intentional Misrepresentation)

27. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

28. Defendants had a duty to truthfully represent to the medical community, and to the Plaintiff, Plaintiff's healthcare providers, and the FDA, that the Wright Hip System had been properly tested and found to be safe and effective for its intended use.

29. Defendants, and each of them, represented to Plaintiff that an important fact was true. Specifically, Defendants represented that the metal-on-metal Wright Hip System orthopaedic implant was a safe and effective orthopaedic hip implant that would not fail before the standard 15-20 year lifespan of an orthopaedic hip implant and would not cause pain, popping, grinding, lack of mobility, metal sensitivity, loosening of the prosthesis, infection, dislocation, bone fracture, high metal ion levels in their bloodstreams, cyst formation, and the necessity for revision surgery to explant the metal-on-metal Wright Hip System orthopaedic implant and replace it with other products.

30. Defendants' representations were false.

31. Defendants, and each of them, knew that the representations were false when they made them or made the representations recklessly without regard for the truth.

32. Defendants, and each of them, intended that Plaintiff rely on their representations.

33. Plaintiff reasonably relied on the representations of Defendants, and each of them.

34. Plaintiff suffered the harm described herein and incorporated herein.

35. Plaintiff's reliance on Defendants' representations was a substantial factor in causing Plaintiff's harm.

36. In taking the actions and omissions that caused these damages, Defendants, and each of them, are guilty of malice, oppression, and fraud, and Plaintiff is therefore entitled to seek and recover punitive damages.

NINTH CLAIM FOR RELIEF

(Negligent Misrepresentation)

37. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

38. Defendants had a duty to truthfully represent to the medical community, and to the Plaintiff, Plaintiff's healthcare providers, and the FDA, that the Wright Hip System had been properly tested and found to be safe and effective for its intended use.

39. Defendants, and each of them, represented to Plaintiff that an important fact was true. Specifically, Defendants represented that the metal-on-metal Wright Hip System orthopaedic implant was a safe and effective orthopaedic hip implant that would not fail before the standard 15-20 year lifespan of an orthopaedic hip implant and would not cause pain, popping, grinding, lack of mobility, metal sensitivity, loosening of the prosthesis, infection, dislocation, bone fracture, high metal ion levels in their bloodstreams, cyst formation, and the necessity for revision surgery to explant the metal-on-metal Wright Hip System orthopaedic implant and replace it with another product.

40. Defendants' representations were false.

41. Although Defendants, and each of them, may have honestly believed that the representations were true, Defendants had no reasonable grounds for believing the representations were true at the time they made the representations.

42. Defendants, and each of them, intended that Plaintiff rely on their representations.

43. Plaintiff reasonably relied on the representations of Defendants, and each of them.

44. Plaintiff suffered the harm described herein and incorporated herein.

45. Plaintiff's reliance on Defendants' representations was a substantial factor in causing Plaintiff's harm.

46. In taking the actions and omissions that caused these damages, Defendants, and each of them, are guilty of malice, oppression, and fraud, and Plaintiff is therefore entitled to seek and recover punitive damages.

TENTH CLAIM FOR RELIEF

(Punitive Damages)

47. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

48. The acts of Defendants were attended by circumstances of malice, or willful and wanton conduct, and/or in reckless disregard of the consequences from which malice may be inferred and showed a total disregard for human life and human suffering.

49. The willful and wanton conduct of Defendants was conduct purposefully committed which Defendants must have realized as dangerous, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of Plaintiff

50. Defendants, when they had the opportunity to do so, repeatedly failed to correct a known dangerous condition regarding the metal-on-metal Wright Hip System.

51. Defendants acted willfully, wantonly, and/or recklessly, and in conscious disregard of Plaintiff's rights, and in reckless disregard of patient safety. Plaintiff is therefore entitled to an award of punitive and exemplary damages.

ELEVENTH CLAIM FOR RELIEF

(Utah Consumer Sales Practices Act)

1. Plaintiffs incorporate herein all other allegations in this Complaint.
2. By selling and supplying Wright Hip System for implantation into consumers, Defendants are a "supplier" as defined by Utah Code § 13-11-3(6).
3. The sale of the Wright Hip System for implant to Plaintiff was a sale of goods to a person for his own personal use, and thus was a "consumer transaction" under Utah Code § 13-11-3(2)(a).
4. Defendants indicated, knowingly or intentionally, that the Wright Hip System has certain performance characteristics, uses, or benefits, or that it was particular standard or quality, including: that it would provide a larger angle of coverage than other hip- replacement systems, that no data was available as to any deleterious effects of elevated Cobalt and Chromium ions that had been detected in patients with metal-on-metal hip replacements, that the Conserve Hip Implant

System and its components were FDA-cleared for marketing, and that the Wright Hip System was appropriate for use in active patients. The Wright Hip System does not, in fact, have such characteristics, uses or benefits and is not of the described standard or quality.

5. Defendants' indications in regard to the hip implant's performance characteristics, uses or benefits violated Utah Code § 13-11-4(2)(a) and (b).

6. Plaintiff brings this case as a consumer who has suffered a loss as a result of s violations of the Utah Consumer Sales Practices Act. Because his actual damages exceed \$2,000, he is entitled to recover his actual damages, which include all of his past and future medical costs relating to the revision of left hip replacement, plus court costs under Utah Code § 13-11-19(2).

7. Additionally, Plaintiff also intends to seek reasonable attorney's fees Utah Consumer Sales Practices Act. See Utah Code §13-11- 19(5).

WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, as follows:

1. For general damages in excess of \$300,000 according to proof.
2. For medical and incidental expenses according to proof.
3. For wage loss and loss of earning capacity according to proof.
4. For economic and special damages according to proof.
5. For mental and emotional distress according to proof.
6. For punitive and/or exemplary damages according to proof.
7. For pre-judgment interest according to proof at the time of trial.
8. For costs of suit and attorney fees herein incurred.
9. For restitution and disgorgement of all revenue that Defendants have obtained through the manufacture, marketing, sale and administration of the metal-on-metal Wright Hip System orthopaedic implant;
10. For such other and further relief, both legal and equitable, as the court may deem just and proper.

The exact nature and extent of Plaintiff's damages have not yet been calculated, and Plaintiff will seek leave of Court to amend this complaint to conform to proof at the time of trial.

JURY DEMAND

Pursuant to Rule 38 of the Utah Rules of Civil Procedure, Plaintiff demands a jury trial for all claims so triable.

Dated: November 8, 2021

s/ Gale Pace
GALE PACE

Utah District Court Cover Sheet for All Civil Actions Except Probate Cases

Interpretation. If you do not speak or understand English, the court will provide an interpreter. Contact court staff immediately to ask for an interpreter.

Plaintiff/Petitioner (First)

Gale Pace (Filing Pro Se)

Name

1452 South Hoytsville Road

Address

Coalville, UT 84017

City, State, Zip

435-336-2560

Phone

kateandgale@gmail.com

Email

First Plaintiff/Petitioner's Attorney or Licensed Paralegal Practitioner*

Name

Bar Number

Plaintiff/Petitioner (Second)

Name

Address

City, State, Zip

Phone

Email

Second Plaintiff/Petitioner's Attorney or Licensed Paralegal Practitioner*

Name

Bar Number

Interpretación. Si usted no habla ni entiende el Inglés el tribunal le proveerá un intérprete. Contacte a un empleado del tribunal inmediatamente para pedir un intérprete.

Defendant/Respondent (First)

Wright Medical Technology, Inc.

Name

Address

City, State, Zip

Phone

Email

First Defendant/Respondent's Attorney or Licensed Paralegal Practitioner*

Name

Bar Number

Defendant/Respondent (Second)

Name

Address

City, State, Zip

Phone

Second Defendant/Respondent's Attorney or Licensed Paralegal Practitioner*

Name

Bar Number

*Attorney or LPP addresses provided by Utah State Bar.

Total Claim for Damages \$ _____ **Jury Demand** [X] Yes [] No \$250 [X] Jury Demand

Schedule of Fees: §78A-2-301 (Choose all that apply. See Page 2 for fees for claims other than claims for damages.)

CHOOSE ONE:

- [] No monetary damages are requested (URCP 26: Tier 2)
- [] Damages requested are \$50,000 or less (URCP 26: Tier 1)
- [] Damages requested are more than \$50,000 and less than \$300,000 (URCP 26: Tier 2)
- [] Damages requested are \$300,000 or more (URCP 26: Tier 3)
- [] Domestic relations (URCP 26: Tier 4)
- [X] Damages are unspecified.
Circle one: Tier 1 Tier 2 Tier 3
- [] This case is exempt from URCP 26. (E)

— MOTION TO RENEW JUDGMENT —

\$45 [] Damages \$2000 or less

\$100 [] Damages \$2001 - \$9,999

\$187.50 [] Damages \$10,000 & over

— COMPLAINT OR INTERPLEADER —

\$90 [] Damages \$2000 or less

\$200 [] Damages \$2001 - \$9999

\$375 [] Damages \$10,000 & over

\$375 [X] Damages Unspecified

— COUNTERCLAIM, CROSS CLAIM, THIRD PARTY CLAIM, OR INTERVENTION —

\$55 [] Damages \$2000 or less

\$165 [] Damages \$2001 - \$9999

\$170 [] Damages \$10,000 & over

Choose One

Fee	Case Type
----- APPEALS -----	
\$375 []	Administrative Agency Review
Sch []	Tax Court (Appeal of Tax Commission Decision) Court: Refer to Clerk of Court upon filing.
\$240 []	Civil (78A-2-301(1)(h)) (E)
\$240 []	Small Claims Trial De Novo (E)
\$80 []	Municipal Admin. Determination. (E)
----- GENERAL CIVIL -----	
Sch []	Civil Rights
\$0 []	Civil Stalking (E)
\$375 []	Condemnation/Eminent Domain
Sch []	Contracts
Sch []	Contract: Employment Discrimination
Sch []	Contract: Fraud
Sch []	Debt Collection
\$375 []	Essential Treatment Intervention (62A-15-1203)
Sch []	Eviction/Forcible Entry and Detainer (E)
\$375 []	Extraordinary Relief/Writs
\$375 []	Forfeiture of Property (E)
Sch []	Interpleader
Sch []	Lien/Mortgage Foreclosure
Sch []	Miscellaneous Civil
\$375 []	Post Conviction Relief: Capital (E)
\$375 []	Post Conviction Relief: Non-capital (E)
Sch []	Property Rights
\$375 []	Registry Removal (Gun/White Collar)
Sch []	Sexual Harassment
Sch []	Water Rights
\$375 []	Wrongful Lien
Sch []	Wrongful Termination
----- TORTS -----	
Sch []	Automobile Tort
Sch []	Intentional Tort
Sch []	Malpractice-Medical Tort
Sch []	Malpractice-Legal Tort; Other
Sch []	Premises Liability
Sch []	Asbestos
Sch [X]	Product Liability (NOT Asbestos)
Sch []	Slander/Libel/Defamation
----- DOMESTIC RELATIONS -----	
\$0 []	Protective Orders (E)
\$325 []	Marriage Adjudication (T2)
\$325 []	Divorce/Annulment (T2)
[]	Check if child support, custody or parent-time will be part of decree
[]	Check if Temporary Separation filed

Fee	Case Type
\$325 []	Custody/Visitation/Support (T2)
\$8 []	Vital Statistics §26-2-25 per form
\$130 []	Counterclaim: Divorce/Separate Maintenance
\$130 []	Counterclaim: Custody/Visit/Support
\$170 []	Counterclaim: Paternity/Grandparent Visitation
\$100 []	Domestic Modification (T2)
\$100 []	Counter-petition: Domestic Modification
\$375 []	Grandparent Visitation (T2)
\$375 []	Paternity/Parentage (T2)
\$325 []	Separate Maintenance (T2)
\$35 []	Temporary Separation (E)
\$35 []	Uniform Child Custody Jurisdiction & Enforcement Act (UCCJEA) (E)
\$35 []	Uniform Interstate Family Support Act (UIFSA) (E)
----- JUDGMENTS -----	
\$35 []	Foreign Judgment (Abstract of) (E)
\$375 []	Foreign Country Judgment (E)
\$50 []	Abstract of Judgment/Order of Utah Court/Agency (E)
\$30 []	Abstract of Judgment/Order of Utah State Tax Commission (E)
\$35 []	Judgment by Confession (E)
----- PROBATE -----	
Use the Utah District Court Cover Sheet for Probate Actions for the following:	
Adoptions/foreign adoptions; conservatorships; estate personal rep; foreign probate; gestational agreements; guardianships; minor's settlements; name changes; supervised administration cases; trusts; other probate actions	
----- SPECIAL MATTERS -----	
\$35 []	Arbitration Award (E)
\$0 []	Determination Competency-Criminal (E)
\$150 []	Expungement Petition (E)
\$0 []	Hospital Lien (E)
\$35 []	Judicial Approval of Document: Not Part of Pending Case (E)
\$35 []	Notice of Deposition in Out-of-State Case/Foreign Subpoena (E)
\$35 []	Open Sealed Record (E)
\$50 []	Petition for Adjudication of Priority to Funds on Trustee's Sale
----- OCAP -----	
(Utah Code §78A-2-501)	
\$20 []	Documents prepared using Online Court Assistance Program (OCAP)